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stimulation of gastrointestinal tract growth, improvement in function of the gastrointestinal tract, promotion of the growth of beneficial gastrointestinal bacteria, lowering blood cholesterol, improving glucose tolerance, reducing average blood glucose in non-insulin-dependent diabetics, stimulation of glucose uptake by muscles, inhibition of the binding of bacteria to a host tissue, inhibition of the growth of bacteria, protection against viruses, enhancing activity of antibiotics, antifungal effects, anti-amoebic effects, prevention of tumor development, inhibition of tumor cell growth, inhibition of tumor metastasis, enhancement of natural killer cell toxicity to tumors, improvement in Alzheimer's dementia, antioxidant effects, and reaction against bacterial toxins, said dietary supplement composition comprising a nutritionally effective amount of β -glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides.

REMARKS

I. Status of the Application

Claims 1, 8-17, 19-20 and 24 are pending herein. Claim 18 has been cancelled. Claims 1, 19 and 20 have been amended in accordance with 37 C.F.R. §1.121(c)(1). It is respectfully submitted that amended claims 1, 19 and 20 are supported by the specification as filed and are in condition for allowance or at least in better form for consideration on appeal. Further, claims 1, 19 and 20 do not raise any new issues which require further search or substantial consideration by the Examiner. For these reasons, it is requested that this amendment be entered under the provisions of 37 C.F.R. § 1.116 as it places the application in condition for allowance or at least in better condition for appeal. Favorable consideration and allowance of claims 1, 8-17, 19-20 and 24 in view of the foregoing amendments and the following remarks are respectfully requested.

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II. Rejection Under 35 U.S.C. § 103(a)

Claims 1, 8-17, 19-20 and 24 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,576,015 to Donzis (hereafter referred to as "Donzis '015"), U.S. Patent No. 5,531,989 to Paul (hereafter referred to as "Paul '989") and International Publication No. WO 97/05884 to Plaut (hereafter referred to as "Plaut '884"). As noted above, claim 18 has been cancelled and claims 1, 19 and 20 have been amended. Insofar as this rejection may be applied against the present claims, it is respectfully traversed.

As provided in MPEP § 2143, "[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, under MPEP § 2142, "[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." It is submitted that the Office action does not factually support a prima facie case of obviousness based on the Donzis '015, Paul '989 and Plaut '884 references for the following reasons.

Each of claims 1, 8-17, 19-20 and 24 cover a dietary supplement composition that includes nutritionally effective amounts of β -glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides. As noted in the present application, the components of the claimed compositions help trigger a cascade of immune signaling mechanisms and that glyconutrients such as the complex of essential saccharides carry the immune signals to other cells. See paragraph [0058]. While not being tied to a particular mode of action, the β -glucan, colostrum, lactoferrin and citrus pectin components of the claimed compositions stimulate an immune response and the complex of essential saccharides help to carry the results of the immune response to other cells.

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Donzis '015 discloses the use of beta (1,3) yeast extract glucan particles as nutritional supplements. Contrary to the claimed subject matter, however, Donzis '015 does not disclose or suggest a composition which includes beta (1,3) yeast extract glucan and a complex of essential saccharides. Therefore, Donzis '015 does not disclose or suggest the subject matter of claims 1, 8-17, 19-20 and 24.

Paul '989 discloses an immunoglobulin and fiber-containing composition for use as a dietary supplement for restoring and maintaining gastrointestinal health. Paul '989 discloses that the fiber portion of the dietary supplement may include pectin and fructo-oligosaccharides. Paul '989 also discloses that the dietary supplement may include lactoferrin as an inhibitor of detrimental iron-catalyzed processes. Contrary to the claimed subject matter, however, Paul '989 does not disclose or suggest a composition which includes a complex of essential saccharides. Therefore, Paul '989 does not disclose or suggest the subject matter of claims 1, 8-17, 19-20 and 24.

Plaut '884 discloses an infant formula which includes pasteurized milk, active lactoferrin, and an antibody which specifically binds at least one of an IgA protease and an IgA protease precursor. Contrary to the claimed subject matter, however, Plaut '884 does not disclose or suggest a composition which includes a complex of essential saccharides. Therefore, Plaut '884 does not disclose or suggest the subject matter of claims 1, 8-17, 19-20 and 24.

Accordingly, none of Donzis '015, Paul '989 or Plaut '884 taken alone disclose or suggest the subject matter of any of claims 1, 8-17, 19-20 and 24.

Furthermore, it is respectfully submitted that the combination of Donzis '015, Paul '989 and Plaut '884 is improper. According to MPEP § 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where

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there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Also, the case law is clear that there must be evidence that a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. It is also clear that a rejection cannot be predicated on the mere identification of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *Ecolchem Inc. v. Southern California Edison*, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000). Here, no such evidence has been presented. In addition, there is absolutely no teaching, suggestion or motivation to support the combination of Donzis '015, Paul '989 and Plaut '884.

Finally, the case law makes it clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. See *In re Dembiczak*, 50 USPQ2d, 1614, 1617 (Fed. Cir. 1999). "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight." *Id.* It is respectfully submitted that the only way Donzis '015, Paul '989 and Plaut '884 could be pieced together to defeat

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patentability is indeed to use Applicant's disclosure as a blueprint. Therefore, the combination of references is improper.

In addition, even if there was a motivation or suggestion to combine Donzis '015, Paul '989 and Plaut '884, the resulting composition would lack a complex of essential saccharides as required by the claims. Thus, even if it were proper to combine the disclosures of Donzis '015, Paul '989 and Plaut '884, the result would not be the dietary supplement of claims 1, 8-17, 19-20 and 24.

Accordingly, for the foregoing reasons, it is respectfully submitted that none of Donzis '015, Paul '989 and Plaut '884 disclose or suggest the subject matter of claims 1, 8-17, 19-20 and 24. Moreover, it is respectfully submitted that it is improper to combine any of such references since there is no motivation or suggestion for such combination to achieve the applicant's claimed dietary supplement, and even if there were, the result would not be the dietary supplement of claims 1, 8-17, 19-20 and 24.

Therefore, for all of the foregoing reasons, it is requested that the rejection of claims 1, 8-20 and 24 under 35 U.S.C. §103(a) over the combination of Donzis '015, Paul '989 and Plaut '884, be withdrawn.

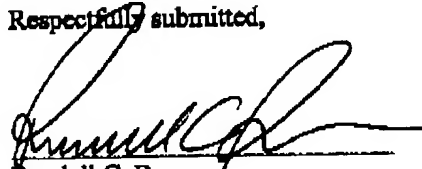
V. Conclusion

It is believed that all matters set forth in the Office Action have been addressed. Applicant has made a diligent effort to advance the prosecution of this application by amending claims 1, 19 and 20 and by submitting arguments in support of the patentability of claims 1, 8-17, 19-20 and 24. In light of the foregoing amendment and remarks, Applicant submits that Claims 1, 8-17, 19-20

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and 24 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited.

Respectfully submitted,



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**ATTACHMENT A: MARKED UP VERSION
OF AMENDMENTS TO THE CLAIMS**

In the Claims:

1. (Twice Amended) A dietary supplement composition for a mammal, comprising a nutritionally effective amount of β -glucan, colostrum, lactoferrin, [and] citrus pectin and a complex of essential saccharides.

19. (Amended) The dietary supplement composition of claim [18] 1, wherein the complex of essential saccharides comprises saccharides provided in oligomeric or polymeric forms as found in:

gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

20. (Twice Amended) A dietary supplement composition for producing in a mammal a first effect selected from the group consisting of regulation of the immune system, regulation of cytokine release, prevention of autoimmune response from intestinal pathogens, promotion of phagocytosis by neutrophils, stimulation of B cell and antibody secretion, inhibition of mast cell enzyme involved in allergic airway response, enhancement of natural killer cell activity, stimulation of muscle protein synthesis, inhibition of muscle protein breakdown, stimulation of wound healing, stimulation of tissue repair, induction of cartilage formation and bone repair, anti-inflammatory effects, enhancement of hematopoietic activity, increase in

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insulin-like growth factor in tissues, antidiarrheal effect on gastrointestinal tract infection, stimulation of gastrointestinal tract growth, improvement in function of the gastrointestinal tract, promotion of the growth of beneficial gastrointestinal bacteria, lowering blood cholesterol, improving glucose tolerance, reducing average blood glucose in non-insulin-dependent diabetics, stimulation of glucose uptake by muscles, inhibition of the binding of bacteria to a host tissue, inhibition of the growth of bacteria, protection against viruses, enhancing activity of antibiotics, antifungal effects, anti-amoebic effects, prevention of tumor development, inhibition of tumor cell growth, inhibition of tumor metastasis, enhancement of natural killer cell toxicity to tumors, improvement in Alzheimer's dementia, antioxidant effects, and reaction against bacterial toxins, said dietary supplement composition comprising a nutritionally effective amount of β -glucan, colostrum, lactoferrin, [and] citrus pectin and a complex of essential saccharides.

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